

Michigan Department of Consumer and Industry Services Health Facilities Evaluation Section P.O. Box 30664 Lansing, MI 48909

RECOMMENDATIONS FOR SAFE HANDLING AND DISPOSAL OF CYTOTOXIC DRUGS

INTRODUCTION

The majority of cytotoxic agents have the potential for causing carcinogenic, mutagenic or teratogenic effects. These agents can have a deleterious effect when coming into contact with the skin, respiratory system, and the eyes. Health care personnel involved with the preparation, handling, administration and disposal of cytotoxic agents, may be at increased health risks.

The following recommendations are intended to reduce the number of opportunities for unnecessary contact with cytotoxic agents by hospital personnel, and prevent contamination of the hospital and community environment.

I. POLICY AND PROCEDURE MANUAL

Written policies and procedures should address the preparation, administration, and disposal of cytotoxic agents and be developed to minimize exposure of personnel to, and contamination of the environment from, cytotoxic agents. The manual should include specific information on personnel practices, equipment and facilities, drug preparation, drug administration, spill management and waste disposal. The development of the manual should be a collaborative effort of all hospital departments involved with cytotoxic agents.

II. PERSONNEL

All personnel involved with cytotoxic agents should receive training regarding the possible health risks associated with exposure to these agents and be instructed in their safe handling and disposal.

Staff members who may be pregnant or breast-feeding should not prepare, administer or otherwise handle cytotoxic agents. Activities related to cytotoxic agents should be distributed among available trained personnel, in order to minimize each employee's daily exposure.

III. DRUG PREPARATION

A. Equipment

A Class II, type B (see attached) vertical laminar flow biological cabinet (hood), should be used for the preparation to cytotoxic agents. The hood should be isolated from traffic patterns of other work stations, preferably in a separate room. The preparation area should be equipped with a handwash sink and an eye wash station.

B. Worker's Apparel and Protection

Gloves must be worn while preparing cytotoxic agents. Care must be taken not to cut, puncture, or tear the gloves. Gloves should be discarded after each use, each hour, when multiple products are being prepared, or when contaminated. Gloves should be tucked into the cuffs of the operator's gown.

A protective garment should be worn when preparing cytotoxic agents. The garment should be made of lint free, low permeability fabric, or coated paper, and must have a closed front, long sleeves, and elastic or knit closed cuffs. The garment must not be worn outside the work area. Disposable gowns are preferred.

C. Drug Preparation Procedures

- Proper aseptic techniques must be followed in the preparation of sterile products to ensure patient safety. The following precautions should be implemented for worker protection:
 - a. Hands must be washed before gloving, and after removing gloves.
 - b. Any liquid remaining in the top of an ampule should be tapped down before the ampule is opened. When breaking the ampule top, a sterile alcohol gauze pad or cotton pledget should be wrapped around the ampule neck to decrease aerosolization and protect against broken glass.
 - c. Vials should be vented as necessary with a hydrophopic filter needle unit to eliminate pressure in the vial.
 - d. When dissolving lyophilized powders contained in ampules, the diluent should be introduced slowly down the side of the ampule wall so as to wet the powder and prevent dusting.
 - e. The air and/or diluent, injected into the vial, should be the smallest amount that will dissolve the drug and permit removal of the solution. This will minimize excessive pressure within the vial.
 - f. Used needles and syringes must not be clipped, crushed or recapped after use, and should be placed in a non-absorbent, puncture proof container.
 - g. Syringes should have Luer-lock fittings. They should be large enough so that they are never more than 3/4 full, but small enough to measure the contents with acceptable accuracy.
 - h. When medications are transported, they should be placed in a sealable plastic bag.

IV. DRUG ADMINISTRATION

A. Apparel

The following items must be worn by personnel administering cytotoxic agents to patients:

- a. Disposable gloves, discarded after each use, or immediately if contaminated.
- b. Occupational Safety and Health Agency (OSHA)-approved splash goggles or protective glasses with wide shields. (Goggles provide superior protection).
- c. A protective garment made of lint free, low-permeability fabric, or coated paper. The garment must have a closed front, long sleeves, and elastic or knit closed cuffs. Disposable gowns are preferred.

B. Administration Sets

Infusion sets and pumps should have Luer-lock fittings. They should be observed for leakage. A plastic backed absorbent pad should be placed under the tubing during administration to contain any leakage. The line should be bled into a sterile alcohol gauze pad, inside a sealable plastic bag.

When priming IV sets or expelling air from syringes, a sterile alcohol gauze should be placed over the fitting or needletip to catch any solution that may be discharged. Alternatively, an empty vial may be used as a receptacle.

Syringes, IV bottles and bags, and pumps should be wiped clean of any drug contamination with an alcohol gauze pad. Hands must be washed after preparing or administering a cytotoxic agent. Waste materials should be placed in a plastic bag, sealed and labeled to indicate cytotoxic waste.

C. Labels

All prepared doses of cytotoxic agents must have a cytotoxic agent warning label.

D. Patient Waste

Gloves should be worn to handle urine and excreta from patients receiving cytotoxic agents¹. Contaminated garments should be changed. Skin contact and splattering should be avoided during disposal.

V. SPILL MANAGEMENT AND WASTE DISPOSAL

A. Direct Contact with Cytotoxic Agents

The following actions, as appropriate, should be taken for overt contamination by cytotoxic agents:

a. Immediately change the contaminated gloves or gown.

- b. Immediately wash the affected skin area with soap and water and have a physician examine the area as soon as possible.
- Immediately flood the affected eye with eyewash designated for that purpose; seek medical attention immediately.
- d. Report incidents involving skin or eye contact in accordance with hospital procedure.

B. Small Spills in Hood

The following actions, as appropriate, should be taken for small spills involving less than 5 ml of cytotoxic agent occurring <u>inside</u> a safety cabinet:

- Leave blower on.
- b. Put on double gloves.
- c. If the spill is liquid, wipe it up with an absorbent pad.
- d. If the spill is a solid, cover it and wipe it with a wet absorbent pad.
- e. Wipe the spilled area three times using sterile water and then 70% isopropyl alcohol.
- f. If the HEPA filter of a hood is contaminated with cytotoxic agents, the unit must not be used. A sign "Do Not Use Contaminated" should be placed on the unit. The filter must be changed as soon as possible according to the manufacturer's instructions by personnel wearing protective gloves, goggles, respirator mask and gown. The person changing the filter must be informed that it has been contaminated by a cytotoxic agent. The filter should be placed in a plastic bag, sealed and labeled to indicate cytotoxic waste.

C. Small Spills Outside Hood

The following actions, as appropriate, should be taken for small spills, involving less than 5 ml of cytotoxic material on counter tops, floors, or other areas <u>outside</u> the hood:

- a. Mark and isolate the area of the spill so that it is not disturbed by other personnel.
- b. Clean up the spill immediately wearing gloves and eye protection.
- c. Non-cleanable items, including any other drugs or supplies that may have been contaminated, should be put in a plastic bag, sealed and labeled to indicate cytotoxic waste.

D. Large Spills

For spills larger than 5 ml or 5 grams, limit the spread of the spill as fast as possible by gently covering with absorbent sheets. Access to the spill area should be restricted. Personnel involved in the clean up area must wear protective apparel as described in Section III B. All contaminated surfaces should be thoroughly cleaned with detergent solution and wiped with clear water. If the spill is in a hood, decontamination of all interior hood surfaces is required. After the cleanup, all contaminated materials including gloves, gowns, and disposable masks should be discarded in a plastic bag. sealed and labeled to indicate cytotoxic waste. (Radiation spill response procedures may serve as an appropriate guide for the management of spills).

E. Waste Collection and Disposal

Routine Waste Collection

Housekeeping personnel should wear gloves when handling cytotoxic agent waste. The waste should be placed in a plastic bag, sealed and labeled to indicate cytotoxic waste. This waste should be kept separate from other waste.

2. Waste Disposal

Cytotoxic solutions should <u>not</u> be flushed into a sanitary sewer system. Cytotoxic waste should <u>not</u> be disposed of in a sanitary landfill. Waste products should be returned to the pharmaceutical supplier for disposal if possible.

Incineration temperature of 1000° centigrade, (1832° F.) are recommended to render cytotoxic substances harmless. Wastes disposed of by incineration may include vials, syringes, unused drugs, gloves, alcohol swabs, and paper towels used to wipe up spills.

BIBLIOGRAPHY

- 1. Stolar, M.H., Power, L.A., & Viele, C.S. Recommendations for handling cytotoxic drugs in hospitals. Am. J. Hosp. Pharm. 1983:40:1163-71.
- 2. Harison, Bruce R. Developing guidelines for working with antineoplastic drugs. Am. J. Hosp. Pharm. 1981:38:1686-93.
- 3. Deans, Keith W. Potential hazards and safety precautions for health care personnel handling cytotoxic agents. Pharm. Dept. Ferris State College. 1983: Feb.
- 4. Power, L.A. Regulated handling or parenteral antineoplastic agents. P&MC Hospitals 1983: July/Aug. 79/82.
- 5. Tortorici, M.P. Precautions followed by personnel involved with the preparation of parenteral antineoplastic medications. Hosp. Pharm. 15:293-301.
- 6. Trester, A.K. & Nader, M.L. Guide for the administration and use of cancer chemotherapeutic agents. Am. J. of Intravenous Therapy & Clinical Nutrition. 1982: Nov.